LOTRIMIN ULTRA ATHLETES FOOT- butenafine hydrochloride cream
Bayer Healthcare LLC.

Lotrimin Ultra ®

Athlete's Foot

Drug Facts

Active ingredient

Butenafine hydrochloride 1%

Purpose

Antifungal

Uses

- cures most athlete's foot between the toes. Effectiveness on the bottom or sides of foot is unknown.
- cures most jock itch and ringworm
- relieves itching, burning, cracking, and scaling which accompany these conditions

Warnings

For external use only

Do not use

- on nails or scalp
- in or near the mouth or the eyes
- for vaginal yeast infections

When using this product do not get into the eyes. If eye contact occurs, rinse thoroughly with water.

Stop use and ask a doctor if too much irritation occurs or irritation gets worse

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- adults and children 12 years and older:
  - use the tip of the cap to break the seal and open the tube
  - wash the affected skin with soap and water and dry completely before applying
  - **for athlete's foot between the toes**: apply to affected skin between and around the toes twice a day for 1 week (morning and night), or once a day for 4 weeks, or as directed by a doctor. Wear well-fitting, ventilated shoes. Change shoes and socks at least once daily.
  - **for jock itch and ringworm**: apply once a day to affected skin for 2 weeks or as directed by a doctor
  - wash hands after each use
- children under 12 years: ask a doctor

Other information

- do not use if seal on tube is broken or not visible
- store between 20° to 25°C (68° to 77°F)

Inactive ingredients

benzyl alcohol, cetyl alcohol, glycerin, glyceryl monostearate SE, polyoxyethylene (23) cetyl ether, propylene glycol dicaprylate, purified water, sodium benzoate, stearic acid, trolamine, white petrolatum

Distributed by Bayer HealthCare LLC, Whippany, NJ 07981

PRINCIPAL DISPLAY PANEL - 12 g Tube Carton

LOTRIMIN ULTRA ®

butenafine hydrochloride cream 1%

ANTIFUNGAL

NET WT 12g (0.42 OZ)

LOTRIMIN ULTRA ATHLETES FOOT

butenafine hydrochloride cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:11523-4338
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BUTENAFINE HYDROCHLORIDE (UNII: R8XA2029ZI) (BUTENAFINE -	BUTENAFINE	1 g

UNII:91Y494NL0X)	HYDROCHLORIDE	in 100 g

Inactive Ingredients

Ingredient Name	Strength
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
GLYCERIN (UNII: PDC6A3C0OX)	
CETETH-23 (UNII: 495CTZ441V)	
PROPYLENE GLYCOL DICAPRYLATE (UNII: 581437HWX2)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TROLAMINE (UNII: 9O3K93S3TK)	
PETROLATUM (UNII: 4T6H12BN9U)	

Product Characteristics

Color	white (white to off white)	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11523-4338-1	1 in 1 CARTON	02/22/2002	
1		12 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:11523-4338-2	1 in 1 CARTON	02/22/2002	
2		15 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:11523-4338-4	1 in 1 CARTON	02/22/2002	
3		30 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA021307	02/22/2002	

Labeler - Bayer Healthcare LLC. (112117283)

Revised: 11/2019 Bayer Healthcare LLC.